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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,702	01/12/2001	Todd Elliott Piper	P048411US0 PHI 1373	2735

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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 02/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/759,702	PIPER, TODD ELLIOTT
	Examiner Ashwin Mehta	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 27 November 2002.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-42 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 1-7 and 20 is/are allowed.

6) Claim(s) 8-19 and 21-42 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objections to claims 1, 5-7 12, 16, 25, and 29 are withdrawn in light of the claim amendments and Applicants' assurances that the ATCC accession number for seed of 37Y15 will be inserted at time of allowance (response received 27 November 2002, page 8, 2<sup>nd</sup> and 3<sup>rd</sup> paragraphs).
3. The rejections of claims 1-10, 12-14, 16-18, 20-23, 25-27, and 29-31 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, are withdrawn in light of the claim amendments and Applicants' assurances that the ATCC accession number for seed of 37Y15 will be inserted at time of allowance.
4. The rejection of claims 1-32 under 356 U.S.C. 112, 1<sup>st</sup> paragraph, requiring deposit of seed of plant 37Y15 is withdrawn, in light of Applicants' assurances that the ATCC accession numbers will be inserted at time of allowance.

***Specification***

5. The specification remains objected to for the inclusion of blank lines on page 7. In the paper submitted 27 November 2002, Applicant provides assurances that seed of plant 37Y15 will be deposited upon receipt of notice of allowance, and the ATCC number will be inserted into the

specification at that time (response, page 8, 2<sup>nd</sup> paragraph). However, the blank lines on page 7 represent the ATCC numbers for the two inbred plants that were crossed to produce 37Y15. Applicants' response does not mention anything about the deposit of the inbreds.

***Claim Objections***

6. Claim 42 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form.

Claim 42 attempts to limit the method of claim 41 by requiring a male sterile maize plant to be produced. However, the method of claim 41 is for producing a male sterile maize plant. The step of producing the plant is inherent to the method of claim 41.

***Claim Rejections - 35 USC § 112***

7. Claims 11, 15, 19, 24, 28, and 32 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed 29 August 2002 under item 3. Applicant traverses the rejection in the paper submitted 27 November 2002. Applicant's arguments were fully considered but were not found persuasive.

Applicant argues that each of the claims recites two requirements: that 37Y15 be an ancestor of the plant, and that the claimed plant be "capable of expressing a combination of at least two 37Y15 traits" selected from a Markush grouping (response, paragraph bridging pages 10-11). However, this issue was not raised in this rejection. Applicant also argues that the

terminology of the adjectives is well known in the art and would be understood by one skilled in the art. Applicant argues that the adjectives clearly characterize and positively recite the degree of expression of the particular traits within Tables 1-4 (response, paragraph bridging pages 10-11). However, the specification does not teach that the traits in Tables 1-4 can be described in the manner in the claims. The specification does not define the separation from outstanding grain yield, for example, from good grain yield. The specification does not define when one would use a particular adjective to recite the degree of expression of a trait in Tables 1-4 and when one would not. That is, what other degrees of expression of the traits would call for the use of the term “excellent” versus “good.”

Applicant argues that the claims now indicate that the plants have 50% of the alleles of 37Y15, and that the plants be able to express a combination of two traits of 37Y15 (response, paragraph bridging pages 10-11). However, the recitation of “50% of its alleles” does not affect the issue raised in this rejection. That the claimed plants are to express a combination of two traits that are also expressed by 37Y15 also does not overcome the rejection, as it is not clear what separates a plant having, for example, excellent yield potential from good yield potential.

Applicant also argues that it is against the policy of the patent statutes to bar patent protection for inventions that are incapable of precise definition and assert that the terms in the claims are as precise as the subject matter of the invention permits (response, page 11, 1<sup>st</sup> full paragraph). However, even if “excellent” is the most precise definition that can be used, it remains unclear when a trait should be defined with that adjective versus “good.”

8. Claims 8, 11, 15, 19, 21, 24, 28, 32, and 38-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 8, 21, and 41: the recitation “genetic factor” renders the claims indefinite. It is not exactly clear what is being referred to by “factor.” It is suggested that “genetic factor” be replaced with --transgene--.

In claims 11, 15, 19, 24, 28, 32, 38, and 39: the recitations “has derived at least 50% of its alleles” in claims 11, 15, 19, 24, 28, and 32, and “deriving at least 50% of its alleles” in claims 38 and 39 render the claims indefinite. It is not clear what is meant by “derived” and “deriving.” Have the alleles been transformed into the claimed plants, did the claimed plants inherit the alleles in crosses, etc.?

In claim 38: the recitation “on average, deriving at least 50%” in line 2 renders the claim indefinite. It is not clear what is being referred to by this recitation. The metes and bounds of the claim are not clear.

In claim 39: the recitation “A 37Y15 maize plant selected from the population of 37Y15 progeny maize plants” renders the claim indefinite. The claim is drawn to plant 37Y15, yet can comprise less than 100% of the alleles of 37Y15.

In claim 40: the recitation “further comprising applying double haploid methods” renders the claim indefinite. The recitation broadens the scope of parent claim 37, which only involves crosses and does not encompass any double haploid method. It is also not clear what double haploid method is being referred to.

9. Claims 9-19 and 22-32 remain and claims 34-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 29 August 2002 under item 3. Applicant traverses the rejection in the paper submitted 27 November 2002. Applicant's arguments were fully considered but were not found persuasive.

Applicant argues that claims 11, 15, 19, 24, 28, and 32 have been amended by adding the threshold, having 50% of the ancestral alleles, that limits the variation permitted among the genus, as well as an assayable function, capable of expressing a combination of at least two traits of 37Y15. Applicant argues that in plants, identifying characteristics are those detectable in the phenotype, which is manifested through gene expression, and that claims to a particular species of invention are adequately described if the disclosure of relevant identifying characteristics is present in the application. Applicants argue that one of ordinary skill is reasonably apprised in knowing that a plant crossed with 37Y15 will result in a plant having half the genetic contribution of 37Y15, and that a further limitation set is that the plants must be capable of expressing a combination of at least two phenotypic characteristics of 37Y15 (response, paragraph bridging pages 13-14). However, the specification does not provide a description of the alleles of 37Y15, nor does it describe the functions that are associated with each of the alleles of 37Y15. The specification does not describe the alleles that govern the expression of any of the traits listed in the claims. As the alleles of 37Y15 are not described, neither are the alleles of its descendants. Indicating that the claimed plants comprise 50% of the alleles of plant 37Y15

does not provide any information concerning the morphological and physiological traits expressed by the claimed plants. That the claimed plants express two traits that are also expressed by 37Y15 does not provide any information concerning the remaining traits, especially since other plants express the traits listed in claims 11, 15, 19, 24, 28, and 32. Further, the new claims encompass plants that can express any traits, none of which are described. Furtherstill, no description of any trait is provided concerning the other parents of the claimed plants. 50% of the alleles of the claimed plants will also be inherited from the other parent, for which no description is provided.

Applicant also argues that the specification supplies an extensive definition and description of “transgene” and transgenes of interest. Applicant argues that the trivial modification introduced by the transgenes to 37Y15 are clearly supported and described in the present application (response, paragraph bridging pages 14-15). However, as written, the claims encompass any and all transgenes, even those that have yet to be isolated and for which descriptions are unknown. Further, the effect that a transgene can have on its host plant depends on the function of its encoded product, among other considerations, and the modification cannot simply be described as “trivial.” A transgene that is a transcription factor, for example, could effect the expression of numerous genes and phenotypes. It is suggested that claims 12 and 25 be amended by listing the types of transgenes that may be introduced, provided that the specification or the prior art indicates that the gene has been isolated, for example transgenes that confer resistance to a plant virus, or which confer male sterility.

Applicants also argue that the claims are definite (response, page 15, 1<sup>st</sup> paragraph). However, definiteness of the claims is not the issue of this rejection.

Further, the specification does not describe any traits of any inbred plants or any progeny plants produced from 37Y15. While plants produced by self or sib pollinating 37Y15 would inherit all of their alleles from 37Y15, the morphological and physiological characteristics of the progeny plants would be different from those of 37Y15, as the genotype of the progeny would not be the same as that of hybrid 37Y15. Furtherstill, Applicants mention that they believe that the subject matter of the new claims has literal support in the specification (response, paragraph bridging pages 13-14). However, the specification does not mention any double haploid method.

The amendments to claims 8 and 21 overcome the rejection for those claims.

10. Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is drawn towards a method of making a hybrid plant designated 37Y15 comprising crossing inbred maize plants GE571367 and GE533418.

Page 7 of the specification indicates that two Pioneer Hi-Bred proprietary inbred lines, GE571367 and GE533418, were crossed to produce hybrid 37Y15. The paper submitted 27 November 2002 provides assurances that seed of 37Y15 will be deposited, in accordance with the deposit rules of 37 CFR 1.801-1.809, as discussed above. However, Applicant's response does not mention the deposit of GE571367 and GE533418.

Since the claimed seeds of are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the seeds are not so obtainable or available, a deposit thereof may satisfy the

requirements of 35 U.S.C. 112. The specification does not disclose a repeatable process to obtain the exact same seeds in each occurrence and it is not apparent if such a seed is readily available to the public.

If the deposit of these seeds will be made under the terms of the Budapest Treaty, then an affidavit or declaration by the Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the deposits were made under the terms of the Budapest Treaty and that the seeds will irrevocably and without restriction or condition be released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds of each type is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposits will not be made under the Budapest Treaty, then in order to certify that the deposits meet the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposits will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) the viability of the biological materials at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposits will be replaced if they should ever become inviable.

***Claim Rejections - 35 USC § 102 & 103***

11. Claims 11, 15, 19, 24, 28, 32 remain and new claims 36, 38, and 39 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kevern (U.S. Patent No. 6,242,673), for the reasons of record stated in the Office action mailed 29 August 2001 under item 6. Applicant traverses the rejection in the paper submitted 27 November 2002. Applicant's arguments were fully considered but were not found persuasive.

Applicant argues that plants 37Y15 and 37M34 are different, and point out a few of the differences, such as in silk color and anther color (page 20, 1<sup>st</sup> full paragraph). Applicant's arguments were found persuasive for the withdrawal of the rejection from claims 1-10, 12-14, 16-18, 20-23 25-27, and 29-32.

The plants encompassed by the remaining claims are different from 37Y15. 37M34 expresses at least two traits listed in the Markush groups of claims 11, 15, 19, 24, 28, and 32. The new claims of 36, 38, and 39 do not place any limitation on the traits that the claimed plants can express, and therefore the claimed plants cannot be distinguished from plants in the art based only on phenotype. It would have been obvious to produce an inbred plant by successive selfing of 37M34, given that Kevern teaches that the objective of commercial maize hybrid line development is to produce new inbreds (col. 3, lines 44-48). The instant claims indicate that the plants either have derived 50%, or all, of its alleles from 37Y15. However, molecular markers unique to the genome of 37Y15 are not known. The Examiner does not have sufficient facts to determine whether the claimed plants and that of the prior are inherently the same. The

Examiner cannot conclude that the claimed subject matter would have been obvious since it cannot be determined whether the plants differ. Where the prior art product seems to be identical, except that the prior art is silent to a characteristic or property claimed, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. See *In re Best* 195 UPSQ 430, 433 (CCPA) 1977).

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### *Contact Information*

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

January 20, 2003



ASHWIN D. MEHTA, PH.D.  
PATENT EXAMINER